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DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service
Food and Drug Administration
SOUTHWEST REGION

Office of the Regional
Food and Drug Director
7920 Elmbrook Drive, Suite 102
Dallas, TX 75247-4982
TELEPHONE: 214-655-8100
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WARNING LETTER

CERTIFIED MAIL
RETURN RECEIPT REQUESTED

00-SWR-WL-64/0

June 12, 2000

Wanda Cumberland
Owner
Nu Weigh
785 Market Street
St. Genevieve, MO 63670

Dear Ms. Cumberland:

The inspection of your tanning facility, Nu Weigh located at 785 Market Street, St. Genevieve, MO 63670 on April 26, 2000, by Investigator Dennis Butcher revealed serious violations of the Federal Food, Drug and Cosmetic Act (the Act). The investigator documented significant items of noncompliance with the Federal Performance Standard for Sunlamp Products as prescribed in Title 21, Code of Federal Regulations, Part 1040.20 (21 CFR 1040.20) in conjunction with a tanning bed in operation at your facility. The inspection indicated noncompliances for the tanning bed manufactured by Geers Elektrogeratebau, model Miami 133F.

The inspection revealed that the tanning bed located at your facility was misbranded within the meaning of Section 502(f) of the Act as a result of actions taken by your firm. There was no user instruction manual or documentation of lamp compatibility available for this tanning bed to provide adequate directions for use in such manner as necessary for the protection of users against potentially harmful exposure to ultraviolet radiation [21 CFR 1040.20(e)(1)]. No timer interval may have an error greater than 10 percent of the maximum timer interval of the product [21 CFR 1040.20(c)(2)].

The above identification of violations is not intended to be an all-inclusive list of deficiencies regarding sunlamp products at your firm. It is your responsibility to ensure that electronic sunlamp products are maintained so that they continue to comply with the provisions of the Act. You should take prompt action to correct these violations. Failure to correct these violations may result in regulatory action, including seizure, injunction, and/or civil money penalties, without further notice.

You should notify this office in writing 15 working days of receipt of this letter, of specific steps you have taken to correct these violations. If corrections cannot be completed within 15 working days, state the reason for the delay and the time frame within which corrections will be completed.

Your reply should be directed to Deborah M. McGee, Radiation Specialist, U.S. Food and Drug Administration, 7920 Elmbrook Drive, Suite 102, Dallas, Texas 75247-4982, telephone (214) 655-8100, ext. 138.

Sincerely,

O. D. Evans
Acting Regional Food and Drug Director
Southwest Region

DM: dm